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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/009,802	01/20/1998	SEAN MCCARTHY	MEI-008-1	7895

7590 04/09/2003
MILLENNIUM BIOTHERAPEUTICS, INC.
620 MEMORIAL DRIVE
CAMBRIDGE, MA 02139

EXAMINER

GUZO, DAVID

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 04/09/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/009,802

Applicant(s)

MCCARTHY, SEAN

Examiner

David Guzo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 61-88 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 61-88 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 28.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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Detailed Action

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/17/03 has been entered.

Claims 61-88 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial or specific asserted utility or a well established utility.

Claims 61-88 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

These rejections are repeated for reasons of record in the previous Office Action (Paper #24) and for reasons outlined below.

Applicant traverses this rejection by asserting that applicants in the instant specification disclose that CRSP-2 (which applicants assert is the same protein as hDkk-4) is a secreted soluble protein involved in modulation of development and differentiation. Applicant asserts

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that later published references (Krupnik et al. and Mao et al.) confirm that CRSP-2 (Dkk4) modulates head induction when hDkk-4 was injected into *Xenopus* embryos and inhibits Wnt signaling thereby inhibiting Wnt-induced axis duplication. With regard to the examiner's previous indication that the specification is silent with respect to Wnt-signaling and the role of CRSP-2, applicant indicates that the specification mentions Wnt-signaling on page 1 of the specification and that CRSP activity may be indirect through interactions with a second protein. With regard to the specification not reciting the Dkk4 protein, applicant notes that Dkk4 is the same protein as CRSP-2 and that nomenclature differences are not relevant to the issue at hand. With regard to the use of words such as "may" or "might" (concerning the functions of Dkk4 or CRSP-2) in the Krupnik et al. reference, applicant indicates that this is just standard language in peer reviewed publications and does not refute applicant's experimental evidence which supports applicant's stated biological functions for CRSP-2.

Applicant's arguments filed 3/17/03 have been carefully considered but are not persuasive. It is noted that a stated specific and substantial utility for a claimed invention must be elucidated in the specification. Applicants cannot rely upon subsequent research to supply a specific and substantial utility which is missing from the specification. Clearly, in the instant specification, applicant does not provide a specific and substantial utility for the CRSP-2 protein. As noted in the previous Office Action (Paper #17, mailed 11/6/00), applicant provides some

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physical characteristics of the CRSP-2 protein but the specification is silent with respect to the specific biological functions of the protein. With respect to Wnt-signaling, the passage recited by applicant makes no mention of the ability of CRSP-2 to inhibit Wnt-signaling. Wnt-signaling proteins are only mentioned as examples of signaling molecules recognized as having a role in development in some organisms.

With regard to the later published papers by Krupnik et al. and Mao et al., it is noted that the function of CRSP-2 (which the examiner agrees is the same protein as hDkk4) appears to involve inhibition of Wnt-signaling (by some unknown mechanism) in experimental systems (i.e. *Xenopus* embryos). The instant specification does not support this utility. At best the instant specification provide only vague generalities concerning the fact that CRSP proteins are secreted proteins and ascribes utility to these proteins based upon their inclusion in the broad family of secreted proteins. Also, with regard to the teachings of the Krupnik et al. and Mao et al. references, it is still unclear what specific function(s) hDkk4 performs in humans. While hDkk4 can apparently inhibit Wnt-signaling in an experimental system (*Xenopus* embryos), it is unclear what function this protein performs in humans.

It is again noted that the specification contains blanks on pp. 4, 14-21, 23, 57. Amendment of the specification to remove or fill in said blanks is required. Applicants is

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reminded that no new matter should be introduced into the specification.

No Claims are allowed.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this

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final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo whose telephone number is (703) 308-1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Faxes may be submitted directly to the examiner at (703) 746-5061.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David Guzo
April 7, 2003

DAVID GUZO
PRIMARY EXAMINER
David Guzo